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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

17

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/024,036

Applicant(s)

BANDARU, RAJASEKHAR

Examiner

David J Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12. 6) ☒ Other: *sequence alignments*.

DETAILED ACTION

Status of the Application

- [1]** Claims 1-22 are pending in the application.
- [2]** Applicant's election without traverse of Group IX, claims 16 and 17, in Paper No. 13, filed June 27, 2003, is acknowledged.
- [3]** Claims 1-15 and 18-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Sequence Compliance

- [1]** This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825; applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicant is required to identify all amino acid sequences of at least 4 L-amino acids and at least 10 nucleotides by a sequence identifier, i.e., "SEQ ID NO:". The specification discloses sequences that have not been identified by a sequence identifier (see page 9, paragraph 37; page 10, paragraphs 40 and 41; page 11, paragraph 43; Figures 3A-C and 4A-C; and the brief description of Figures 3A-C and 4A-C at page 6). If these sequences have not been disclosed in the computer readable form of the sequence listing and the paper copy thereof, applicant must provide a computer readable form copy of the "Sequence Listing" including these sequences, a paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d).

Specification/Informalities

[4] The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification (see pages 7, 24, and 25) is improper. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

[5] The use of the trademarks "Triton®", "Thesit®", "Cremophor EL™", and "GenBank™" has been noted in this application (see pages 51, 73, and 91). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

[6] Claims 16 and 17 are objected to as being dependent upon non-elected claim 1. It is suggested that, for example, applicant amend claim 16 such the claim no longer depends from non-elected claim 1 and no longer recites non-elected subject matter.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[7] Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 16 (claim 17 dependent therefrom) is indefinite in the recitation of "selectively hybridizes". The term "selectively hybridizes" is not defined in the specification and it is unclear as to how identical a nucleic acid probe or primer must be to the complement of a nucleic acid molecule in order for the probe or primer to "selectively" hybridize thereto. Furthermore, while it is acknowledged that the preamble of claim 16 recites, "[a] method for detecting the presence of *a nucleic acid molecule of claim 1*" (italics added for emphasis), the final step of the method of claim 16 recites "determining whether the nucleic acid probe or primer binds to *a nucleic acid molecule in the sample*" (italics added for emphasis). Based on the recitation of *a nucleic acid molecule* in the last step of the claim, the scope of nucleic acids detected by the method is *not* limited to the nucleic acid molecule of claim 1 and it is unclear as to the scope of desired nucleic acid molecules that are detected by the method. It is suggested that applicant clarify the meaning of the term "selectively hybridizes" and amend the term "a nucleic acid" in line 5 of claim 16 to "the nucleic acid".

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[8] Claims 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 16 and 17 are drawn to a method for detecting the presence of a genus of nucleic acids of claim 1 in a sample comprising the steps of: contacting the sample with a genus of nucleic acid probes or primers that selectively hybridize to the nucleic acid molecule and determining whether the nucleic acid

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probe or primer binds to the nucleic acid molecule in the sample, and optionally wherein the sample comprises mRNA molecules and is contacted with a genus of nucleic acid probes.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. While it is acknowledged that the claims are not drawn to nucleic acids and are instead drawn to methods of using nucleic acids, MPEP § 2163 states, "[t]he claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art". In this case, the methods recite nucleic acid probes and primers which are essential to the identification of the nucleic acid of claim 1. However, the specification discloses only two representative species of the genus of recited nucleic acid probes or primers, i.e., a probe or primer consisting of a fragment of the polynucleotide of SEQ ID NO:1, which comprises the open reading frame of SEQ ID NO:3, or a fragment of the complement thereof and only two representative species of nucleic acid molecules identified therewith, i.e., the polynucleotide of SEQ ID NO:1, which comprises the open reading frame of SEQ ID NO:3, and the complement thereof. The specification fails to describe any additional representative species of the recited genus of nucleic acids, probes, or primers. In the instant case, the recited genus of nucleic acid probes and primers encompasses species that are widely variant in both structure and function that have not been disclosed in the specification that would detect nucleic acids also not disclosed in the specification including (but not limited to) genomic sequences, allelic

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variants, and nucleic acid variants including those variants encoding polypeptides having function other than the asserted kinase activity of SEQ ID NO:2, e.g., non-functional polypeptides and polypeptides having activities other than that of SEQ ID NO:2. As such, the disclosure of the representative species of SEQ ID NO:1, which comprises SEQ ID NO:3, the complement thereof, and a probe or primer consisting of a fragment thereof is insufficient to be representative of the attributes and features of *all* species encompassed by the recited genus of nucleic acid molecules, probes, and primers used in the claimed method. Given the lack of description of a representative number of nucleic acid molecules, probes, and primers, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[9] Claims 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting the presence of SEQ ID NO:1 or 3 or the complement thereof in a sample comprising the steps of: contacting the sample with a probe consisting of a fragment of SEQ ID NO:1 or 3 or the complement thereof and determining whether the nucleic acid probe or primer binds to the nucleic acid molecule in the sample, does not reasonably provide enablement for a method for detecting the presence of *all* nucleic acids of claim 1 in a sample comprising the steps of: contacting the sample with *any* nucleic acid probe or primer that selectively hybridizes to the nucleic acid molecule and determining whether the nucleic acid probe or primer binds to the nucleic acid molecule in the sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404

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(Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

- The claims are overly broad in scope: The claims are so broad as to encompass a method for selectively detecting the presence of *all* nucleic acids of claim 1 – including fragments and variants of SEQ ID NO:1 and 3 that would encode proteins having activity other than the asserted kinase activity - in a sample comprising the steps of: contacting the sample with *any* nucleic acid probe or primer that selectively hybridizes to the nucleic acid molecule and determining whether the nucleic acid probe or primer binds to the nucleic acid molecule in the sample. The broad scope of nucleic acid molecules selectively detected and probes and primers used in the method of claim 16 are not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acid molecules, probes, and primers broadly encompassed by the claimed method. In this case the disclosure is limited to a method for detecting the presence of the nucleic acid of SEQ ID NO:1 or 3 or the complement thereof in a sample comprising the steps of: contacting the sample with a probe consisting of a fragment of SEQ ID NO:1 or 3 or the complement thereof and determining whether the nucleic acid probe or primer binds to the nucleic acid molecule in the sample.

- The lack of guidance and working examples: The specification provides only a single working example of a nucleic acid molecule of claim 1, i.e., SEQ ID NO:1, which comprises SEQ ID NO:3, from which primers and probes can be designed for use in nucleic acid detection assays. The specification fails to provide guidance for detecting any other nucleic acids as broadly encompassed by claim 1.

Furthermore, the specification fails to provide guidance regarding the design of primers and probes that would selectively detect a *specific* nucleic acid sequence without also detecting other homologous sequences. The single disclosed working example fails to provide the necessary guidance that would be

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required to make probes and primers that would detect a *specific* nucleic acid without also detecting other sequences. Without such guidance for designing and making those probes and primers that would distinguish a single target nucleic acid from other non-specific nucleic acids, one of skill in the art cannot practice the claimed method to *specifically* detect the entire scope of nucleic acids as broadly encompassed by claim 1.

- The high degree of unpredictability in the art: The nucleotide sequence of a nucleic acid probe or primer and the conditions under which the probe or primer is allowed to hybridize determines the corresponding nucleic acid sequence(s) that is/are detected thereby. Predictability of which changes can be made to a nucleic acid probe or primer in combination with the required hybridization conditions for selective target detection with an expectation of the probe or primer having the ability to *selectively* detect a desired nucleic acid - in this case a nucleic acid encoding a calmodulin dependent kinase - is *highly* unpredictable, particularly in view of the lack of guidance and/or working examples of nucleic acid molecules and probes and primers for detection thereof. Furthermore, even those primers and probes that are identical to or complementary to a given sequence can detect nucleic acids other than the desired target sequence and, without the necessary guidance for designing probes and primers that selectively detect a *specific* sequence, it is highly unpredictable as to whether or not a given probe or primer will have the ability to detect a *specific* sequence without also detecting other homologous sequences.

- The state of the prior art supports the high degree of unpredictability: The state of the art provides evidence for the high degree of unpredictability in detecting a *specific* target nucleic acid using *any* probe or primer that selectively hybridizes to the nucleic acid molecule. For example, Verploegen et al. (*Blood* 96:3215-3223) teach PCR using degenerate primers based on kinase consensus sequences to amplify granulocyte cDNA (page 3216, left column, bottom). The degenerate primers of Verploegen et al. would selectively hybridize to any nucleic acid having the consensus sequence, and would not have the ability to distinguish and detect a desired nucleic acid from other closely related sequences. However,

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using a probe with a specifically defined nucleotide sequence, Verploegen et al. were able to isolate a nucleic acid that is 100% identical to SEQ ID NO:3. Thus, in order to specifically detect a desired sequence, one must design a probe or primer such that the probe or primer is *specific* for the given sequence. Without such specificity, it is highly unpredictable as to whether a given probe or primer has the ability to distinguish a desired nucleic acid from other homologous sequences in the sample.

- The amount of experimentation required is undue: While methods of detecting a specific single target nucleic acid sequence are known in the art, e.g., hybridization and PCR, such methods require a probe or primers with the ability to *specifically* distinguish between a target nucleic acid and other non-specific nucleic acids that are present in a given sample, even those that share homology to the target sequence. In the instant case, designing probes or primers which could distinguish a *specific* sequence from any of the others as broadly encompassed by claim 1 under any given hybridization conditions would require undue experimentation. Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

[10] Applicant's claim for domestic priority under 35 USC § 119(e) to provisional application

60/258,222, filed December 22, 2000, is acknowledged. The sequences of SEQ ID NO:1-3 of the instant application are disclosed in provisional application number 60/258,222 as SEQ ID NO:1-3, respectively.

Applicant is granted the benefit of the earlier filing date of provisional application 60/258,222 to the extent this provisional application provides support for the claimed subject matter. Accordingly, the following rejection(s) have been made based on a priority date of December 22, 2000.

[11] Claims 16 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Verploegen et al.

(*Blood* 96:3215-3223). Claim 16 is drawn to a method for detecting the presence of a nucleic acid of claim 1 in a sample comprising the steps of: contacting the sample with a nucleic acid probe or primer that selectively hybridizes to the nucleic acid molecule and determining whether the nucleic acid probe or primer binds to the nucleic acid molecule in the sample. Claim 17 limits the method to a sample comprising mRNA molecules that is contacted with a nucleic acid probe. Verploegen et al. teach a nucleic acid (page 3218, Figure 1) having a sequence that is 100% identical to SEQ ID NO:3 (see attached sequence comparison). The nucleic acid of Verploegen et al. was identified by first generating a specific probe by PCR and using this probe to screen a λ ZAPII eosinophilic library to detect their nucleic acid by plaque hybridization (see page 3216, left column, bottom to right column, top). Verploegen et al. teach that the PCR probe was transcribed into a labeled RNA probe and used to detect and quantify mRNA levels in different cell types by RNase protection involving hybridization of the RNA probe to its target sequence (page 3216, right column, bottom). This anticipates claims 16 and 17 as written.

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[12] Claim 16 is rejected under 35 U.S.C. 102(e) as being anticipated by Donoho et al. (US Patent 6,602,698). Claim 16 is drawn to a method for detecting the presence of a nucleic acid of claim 1 as described in item 12 above. Donoho et al. teach a nucleic acid having a sequence that is 100% identical to SEQ ID NO:3 (see SEQ ID NO:3 of Donoho et al.). Donoho et al. teach the nucleic acid of SEQ ID NO:3 can be used to generate PCR primers or probes for use in screening nucleic acid libraries to detect the presence of their nucleic acid or in monitoring gene expression (column 3) using, e.g., the disclosed hybridization conditions (column 4). This anticipates claim 16 as written.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

[13] Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donoho et al. (US Patent 6,602,698) in view of Ausubel et al. ("Current Protocols in Molecular Biology", pages 4.1.1 and 4.9.1 to 4.9.8, John Wiley and Sons, New York, 1987). Claim 17 is drawn to a method for detecting the presence of a nucleic acid of claim 1 as described in item 12 above.

Donoho et al. disclose the teachings as described in item 14 above. Donoho et al. do not teach detecting their nucleic acid in a sample comprising mRNA.

Ausubel et al. teach that in order to elucidate the regulatory properties of a gene, it is necessary to know the structure and amount of the RNA produced from that gene (page 4.0.3) Ausubel et al. teach a method for determining the amount and size of intact RNA is by northern hybridization using a labeled nucleic acid probe (pages 4.9.1-4.9.8).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of Donoho et al. and Ausubel et al. to radioactively label a fragment of the

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complement of SEQ ID NO:3 and use this probe to detect the level of mRNA present in a sample. One would have been motivated to radioactively label a fragment of the complement of SEQ ID NO:3 and use this probe to detect the level of mRNA present in a sample in order to know the amount of RNA produced from the corresponding gene as taught by Ausubel et al. One would have a reasonable expectation of success for labeling a fragment of the complement of SEQ ID NO:3 and using this probe to detect the level of mRNA present in a sample because of the results of Donoho et al. and Ausubel et al. Therefore, claim 17, drawn to a method for detecting the presence of a nucleic acid of claim 1 as described in item 12 above would have been obvious to one of ordinary skill in the art.

Conclusion

[14] Status of the claims:

- Claims 1-22 are pending.
- Claims 1-15 and 18-22 are withdrawn from consideration.
- Claims 16 and 17 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman
Patent Examiner
Art Unit 1652

[Signature] 08/21/03